DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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October 22, 2014

LIPOSCIENCE, INC.
SUZETTE WARNER
SENIOR MANAGER, REGULATORY AFFAIRS
2500 SUMNER BLVD.
RALEIGH NC 27616

Re: K133849
Trade/Device Name: Vantera Clinical Analyzer; NMR Lipoprofile® test on Vantera Clinical Analyzer
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: II
Product Code: NSU, MRR, LBS, CDT
Dated: September 19, 2014
Received: September 22, 2014

Dear Ms. Suzette Warner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133849

Device Name
Vantera® Clinical Analyzer, NMR LipoProfile® test on Vantera® Clinical Analyzer

Indications for Use *(Describe)*
The Vantera® Clinical Analyzer is an automated laboratory test analyzer which measures the 400 MHz proton nuclear magnetic resonance (NMR) spectrum of clinical samples to produce signal amplitudes, converting these signal amplitudes to analyte concentration. The device includes a 400 MHz NMR spectrometer and software to analyze digitized spectral data. This instrumentation is intended to be used with NMR based assays to detect multiple analytes from clinical samples.

The NMR LipoProfile® test, when used with the Vantera® Clinical Analyzer, an automated NMR spectrometer, measures lipoprotein particles to quantify LDL particle number (LDL-P), HDL cholesterol (HDL-C), and triglycerides in human serum and plasma using nuclear magnetic resonance (NMR) spectroscopy. LDL-P and these NMR-derived concentrations of HDL-C and triglycerides are used in conjunction with other lipid measurements and clinical evaluation to aid in the management of lipoprotein disorders associated with cardiovascular disease.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary K133849

LIPOSCIENCE

I. SUBMITTER

LipoScience, Inc.
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Raleigh, NC 27616

Phone: (919) 256-1326
Fax: (919) 256-1149

Contact Person: Suzette Warner

Date Prepared: September 18, 2014

II. DEVICE

Name of Device: Vantera® Clinical Analyzer
Common Name: *NMR LipoProfile*® test on Vantera® Clinical Analyzer
Classification Names:

Instrumentation for clinical multiplex test system, 21 CFR 862.2570, Product Code NSU
Lipoprotein test system, 21 CFR 862.1475, Product Code MRR and LBS
Triglyceride test system, 21 CFR 862.1705, Product Code CDT

Panel: Clinical Chemistry (75)

III. PREDICATE DEVICE

Legally Marketed Device to which Equivalence is Claimed (Predicate Device):

NMR LipoProfile test on Vantera Clinical Analyzer k113830

IV. DEVICE DESCRIPTION

The Vantera Clinical Analyzer is a clinical laboratory analyzer that employs nuclear magnetic resonance spectroscopic detection to quantify multiple analytes in biological fluid specimens, specifically blood plasma and serum.

The Vantera Clinical Analyzer system design is divided into 3 major subassemblies: a sample handling assembly, an NMR subassembly, and an enclosure. The Vantera Clinical Analyzer control system is distributed across three separate computers:

- The Host (1 U) controls user interface, data handling, results calculation, system startup and shutdown.
- The Process Control (4U) schedules and manages all activities required to process a sample, controls all hardware in the sample handling subsystem.
- The NMR Control Computer controls all magnet operations. Two of these computers are contained within the Sample Handling Subassembly (1 U and 4U) and one in the NMR Subassembly (NMR Console).

The NMR LipoProfile test involves measurement of the 400 MHz proton NMR spectrum of a plasma/serum sample, deconvolution of the composite signal at approximately 0.8 ppm to produce signal amplitudes of the lipoprotein subclasses that contribute to the composite plasma/serum signal, and conversion of these subclass signal amplitudes to Lipoprotein subclass concentrations. The -0.8 ppm plasma NMR signal arises from the methyl group protons of the lipids carried in the LDL, HDL and VLDL subclasses of varying diameters. The NMR signals from the various lipoprotein subclasses have unique and distinctive frequencies and lineshapes, each of which is accounted for in the deconvolution analysis model. Each subclass signal amplitude is proportional to the number of subclass particles emitting the signal, which enables subclass particle concentrations to be calculated from the subclass signal amplitudes derived from the spectral deconvolution analysis. LDL subclass particle concentrations, in units of nanomoles of particles per liter (nmol/L), are summed to give the reported total LDL particle concentration (LDL-P). By employing conversion factors assuming that the various lipoprotein subclass particles have cholesterol and triglyceride contents characteristic of normolipidemic individuals, HDL cholesterol and triglyceride concentrations are also derived.

V. INDICATIONS FOR USE

For the Instrument
The Vantera Clinical Analyzer is an automated laboratory test analyzer which measures the 400 MHz proton nuclear magnetic resonance (NMR) spectrum of clinical samples to produce signal amplitudes, converting these signal amplitudes to analyte concentration. The device includes a 400 MHz NMR spectrometer and software to analyze digitized spectral data. This instrumentation is intended to be used with NMR based assays to detect multiple analytes from clinical samples.

For the Asaay
The *NMR LipoProfile®* test, when used with the Vantera® Clinical Analyzer, an automated NMR spectrometer, measures lipoprotein particles to quantify LDL particle number (LDL-P), HDL cholesterol (HDL-C), and triglycerides in human serum and plasma using nuclear magnetic resonance (NMR) spectroscopy. LDL-P and these NMR-derived concentrations of HDL-C and triglycerides are used in conjunction with other lipid measurements and clinical evaluation to aid in the management of lipoprotein disorders associated with cardiovascular disease.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified Vantera Clinical Analyzer is as safe and effective as the predicate device, k113830. The Vantera has the same intended use as the predicate device. The differences between the candidate device and the predicate device raise no new issues of safety or effectiveness.

	Vantera Clinical Analyzer **(Predicate)**	***Vantera Clinical Analyzer*** **(Candidate Device)**
Similarities		
510(k) Number	K113830	K133849
Intended Use / Indications for Use (Assay)	The *NMR LipoProfile®* test, when used with the Vantera® Clinical Analyzer, an automated NMR spectrometer, measures lipoprotein particles to quantify LDL particle number (LDL-P), HDL cholesterol (HDL-C), and triglycerides in human serum and plasma using nuclear magnetic resonance (NMR) spectroscopy. LDL-P and these NMR-derived concentrations of HDL-C and triglycerides are used in conjunction with other lipid measurements and clinical evaluation to aid in the management of lipoprotein disorders associated with cardiovascular disease.	same
Instrument Intended Use	The Vantera® Clinical Analyzer is an automated laboratory test analyzer which measures the 400 MHz proton nuclear magnetic resonance (NMR) spectrum of clinical samples to produce signal amplitudes, converting these signal amplitudes to analyte concentration. The device includes a 400 MHz NMR spectrometer and software to analyze digitized spectral data. This instrumentation is intended to be used with NMR based assays to detect multiple analytes from clinical samples.	same
Technology	Nuclear magnetic resonance	same
User Interface	Touch Screen GUI	same
System Bulk Fluids	Stored on board	same
Specimen Sampling and Handling	Serum/Plasma Samples are diluted onboard system	same
System Calibration	System calibration required to assess and correct homogeneity of the magnetic field	same

	Vantera Clinical Analyzer **(Predicate)**	***Vantera Clinical Analyzer*** **(Candidate Device)**
Safety Standards for Electrical Equipment	IEC 61010-1: 2001 2nd Edition	same
Specimen Identification	Barcode reader entry of sample ID	same
Materials (Consumables)	Diluent 1, WASH, NMR Reference Standard, Liquicheck Lipid Controls	same
Differences		
NMR Console	MR-400	MR-400-DD2
NMR Control Software	VnmrJ Software v3.0 Operating System: Linux 5.3	VnmrJ Software v3.2 Operating System: Linux RHEL6.3
Instrument Enclosure	Sheet Metal and Fiberglass	Sheet Metal and polyurethane
Cryogen Monitor	Separate helium and nitrogen monitors	Combination of helium monitor and nitrogen monitor into one unit
Fluidics Daughter Board	No rinse pump feedback monitoring	Rinse pump tachometer used to monitor rinse pump

Performance data further demonstrate that the Vantera Clinical Analyzer is as safe and effective as its predicate, k11383.

LDL-P (nmol/L)	**Vantera Clinical Analyzer (Predicate Device) k113830**			**Vantera Clinical Analyzer (Candidate Device)**		
Measuring Range	300 - 3500			300 - 3500		
LoB	0			0		
LoD	40.7			50.1		
LoQ	132			154.7		
Linearity Regression	y= 1.02x + 7.82			y= 0.99x + 106.6		
Linearity R^2	0.995			0.997		
Linear Range	225 - 4322			290 - 3524		
Within-Run Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	842.6	1309.5	1837.7	706.2	1308.6	2249.9
SD	48.5	39.1	50.3	54.63	72.85	58.35
CV%	5.8	3.0	2.7	7.7	5.5	2.6
Within-Lab Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	988.6	1266.7	1943.5	729.0	1338.2	2234.4
SD	48.84	32.57	63.42	50.8	88.69	59.92
CV%	5.3	4.0	3.9	7.0	6.8	2.7
Method Comparison	Linear regression: y=1.03x - 36.60, r=0.978			Deming fit: y= 43.44 + 0.98x r = 0.988		
Medical Decision Limits	1000, 1300 and 1600			same		
Sample Type	Serum and Plasma			same		
Carryover	No significant trending of the results and no persistent bias relative to the reference mean for either the low or high pools			same		
Interference Study	7 Endogenous and 23 Exogenous substances were tested. Salicylic acid at ≥ 1.3mmol/L was determined to interfere with LDL-P and Clopidogrel hydrogensulfate at ≥ 95.7 µmol/L was determined to interfere with LDL-P			7 Endogenous and 23 Exogenous substances were tested. Clopidogrel (Plavix) interferes with test results at the therapeutic doses of 95.7µmol/L Salicylic acid interferes with test results at therapeutic doses of 1.3 mmol/L. Fenofibrate interferes with test results at therapeutic doses of 31 µmol/L. Menhaden oil interferes with test results at therapeutic doses of 0.6 mg/mL.		

TG (mg/dL)	**Vantera Clinical Analyzer (Predicate Device) k113830**			**Vantera Clinical Analyzer (Candidate Device)**		
Measuring Range	5- 1100			10 - 1100		
LoB	1.1			1.2		
LoD	2.3			2.3		
LoQ	4			4.8		
Linearity Regression	y= 1.01x – 0.40			y= 1.01x – 1.7		
Linearity R^2	1.0			1.0		
Linear Range	4 – 1346			4 - 1355		
Within-Run Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	70.1	169.2	356.1	72.4	168.3	286.1
SD	1.6	3.5	4.2	1.93	1.55	1.62
CV%	2.3	2.1	1.2	2.7	0.9	0.6
Within-Lab Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	68.8	166.3	352.2	71.4	162.4	274.9
SD	1.59	3.92	9.36	2.39	2.44	6.94
CV%	2.3	2.4	2.7	3.3	1.5	2.5
Method Comparison	Linear regression: y=1.00x + 0.92, r=0.998			Deming fit: Y= 1.01x + 0.30 r=1.00		
Sample Type	Serum and Plasma			Serum and Plasma		
Carryover	No significant trending of the results and no persistent bias relative to the reference mean for either the low or high pools.			same		
Interference Study	7 Endogenous and 23 Exogenous substances were tested, no interference was found			same		

HDL-C (mg/dL)	Vantera Clinical Analyzer (Predicate Device) k113830			Vantera Clinical Analyzer (Candidate Device)		
Measuring Range	7 - 140			7 - 140		
LoB	2.7			3.2		
LoD	3.5			4.4		
LoQ	4			4.4		
Linearity Regression	y= 1.04x – 0.35			y= 1.02x – 0.63		
Linearity R^2	1.0			1.0		
Linear Range	6 - 148			5 - 168		
Within-Run Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	29.1	51.1	86.9	28.75	55.2	90.0
SD	1.17	1.43	2.29	0.44	0.41	1.62
CV%	4.0	2.8	2.6	1.5	0.7	1.8
Within-Lab Precision	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Mean	28.9	50.7	85.2	27.0	52.4	87.9
SD	0.80	1.02	1.51	0.71	1.02	2.52
CV%	2.8	2.0	1.8	2.7	1.9	2.9
Method Comparison	Linear regression: y=1.04x-1.20, r=0.989			Deming fit: y= -1.36 + 1.01x - r=0.998		
Sample Type	Serum and Plasma			Serum and Plasma		
Carryover	No significant trending of the results and no persistent bias relative to the reference mean for either the low or high pools.			same		
Interference Study	7 Endogenous and 23 Exogenous substances were tested, no interference was found.			same		

VII. CONCLUSION

A risk analysis was performed to identify any new risks due to the hardware and software modifications to device. Based on this risk analysis, verification and validation testing was performed that included software verification and validation testing, as well as analytical validation studies. This verification and validation testing included:

- Software validation testing to ensure that hardware and software modifications to the device did not affect the sample handling performance of the device.
- Analytical validation performance testing to ensure that the hardware and software modifications did not affect the accuracy of test results. This testing included precision, method comparison, linearity, limits of detection, interference and carry over studies.

The results of these verification and validation studies support that the performance of the modified device is substantially equivalent to that of the predicate device and that the differences in performance do not impact the safe use of the device.